Over-The-Counter Drug Monograph System- Past, Present and Future; Public Hearing

The purpose of this public hearing is to obtain input on how to improve or alter the current OTC Monograph Process for reviewing OTC drugs marketed under the OTC Drug Review. This hearing is being held to obtain information from the public on the strengths and weaknesses of the current OTC Monograph Process, and to obtain ideas about modifications or alternatives to this process.

Agenda

March 25, 2014

9:00 am – Welcome – Janet Woodcock, MD, Director, Center for Drug Evaluation and Research

9:15 am – Opening Remarks –Robert Guidos, JD, Senior Advisor to the Director, CDER

9:30 am – William Soller, University of California, San Francisco

9:45 am – Scott Melville, David Spangler, Barbara Kochawaski, Consumer Healthcare Products Association

10:15 am – Scott Bass, SidleyAustin, LLP

10:30 am - Break

10:45 am – Lauren Quinn, Novartis Consumer Health Inc.

11:00 am – Greg Collier, Procter and Gamble Company

11:15 am - Elizabeth Anderson, Personal Care Products Council

11:30 am - Lunch

12:30 pm – Leo Beletsky, Northeastern University School of Law & Bouve College of Health

12:45 pm - Greg O'Neill, The Gerontological Society of America

1:00 pm - Craig Weiss, Independent Cosmetic Manufacturing and Distribution, ICMAD

1:15 pm – Gabrielle Cosel, The PEW Charitable Trusts

1:30 pm - Jim Czaban, Wiley Rein

1:45 pm – Valerie Ramsey, CB Fleet Company, Inc.

2:00 pm – Break

2:15 pm - Lynne Szczepaniak, Ed Kuffner, McNeil Consumer Healthcare Products

2:35 pm - Kathleen Neville, MD, American Academy of Pediatrics

2:50 pm - Peter Barton Hutt

3:05 pm – Closing Remarks

March 26, 2014

9:00 am - Opening Remarks – Robert Guidos

9:15 am – Daniel Hussar, Philadelphia College of Pharmacy

9:30 am - David Steinberg, Steinberg and Associates

9:45 am – Richard Kingham, Covington and Burling, LLP

10:00 am – Ann Begley, Morgan, Lewis, Brockius

10:15 am – David Schoneker, IPEC-Americas

10:30 am– Closing Remarks

FDA Panel

Presiding Officer

Robert Guidos, JD

Panelists

- Carol Bennett, JD, Acting Director, Office of Compliance, CDER
- Thomas J. Cosgrove, JD, Director, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER
- Peter Diak, PharmD, MPH, Team Leader, Division of Pharmacovigilance II, Office of Surveillance and Epidemiology, CDER
- Leslie Kux, JD, Assistant Commissioner for Policy, Office of Policy, Planning and Legislation, Office of the Commissioner
- Theresa M. Michele, MD, Director, Division of Nonprescription Clinical Evaluation, CDER